

DECLARATION UNDER 37 C.F.R. 1.132

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Title: COMPOSITIONS AND METHODS FOR CRYOPRESERVATION OF PERIPHERAL BLOOD LYMPHOCYTES

cryopreservation composition, the cooling rate for optimal cryopreservation between a highly permeable cell such as a red blood cell will be approximately 1000 times that of a hamster ova.

10. Thus, the concentration of AG to be employed in a particular cryopreservation medium varies with cell type and is based on the biophysical properties of the cell type.

11. Therefore, a general disclosure of a method of freezing which employs an AG-containing solution or an AG-containing composition of freezing medium useful for one cell type (WO 97/35472) does not enable a method or composition for another cell type due to differences in the biophysical and biological properties of each particular type of cell. Likewise, a disclosure that a solution containing AG is useful to separate platelets and white blood cells from whole blood based on the physical density of the solution (the LAREX Material Data Safety Sheet) does not enable a composition or method for cryopreservation of freshly isolated lymphocytes, stem cells, or lymphocytes which have been modified *ex vivo*.

12. I further declare that all statements made herein of my own knowledge are true, and that all statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 21 AUG 01By: 

Allison Hubel, Ph.D.